GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

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Alice E. Till, Ph.D.
President

April 30, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Draft Guidance for Industry on Placing the Therapeutic Equivalence Code on Prescription Drug labels and Labeling [Docket No. 98D-1266]

Dear Sir/Madam:

On behalf of the Generic Pharmaceutical Industry Association (GPIA) I would like to supplement our comments on the subject, draft guidance, submitted April 1, 1999.

Subsequent to submission of the original GPIA comments to the docket, a GPIA member company raised two issues which should be considered when finalizing this draft guidance. First, it was noted that although the cost of placing the proposed additional information on the labels of *future* or *newly* approved drug products is negligible, for already marketed products, redesigning and changing labels could prove quite costly. Second, the implications of changes in the therapeutic rating due to innovator changes to a reference product are unclear. Would this mean a recall since the information on the generic label would no longer be accurate? One possible alternative for minimizing "cost" and "change" implications is to *allow* a manufacturer to *choose* to limit the proposed therapeutic equivalence labeling (innovator drug name and Orange Book rating) to the generic stock bottle.

Thank you for your consideration of these additional comments.

Sincerely,

Alice E. Till, Ph.D.
President

Cc M. Samson, Chair GPIA
J. Phillips, CDER, FDA

98D-1266

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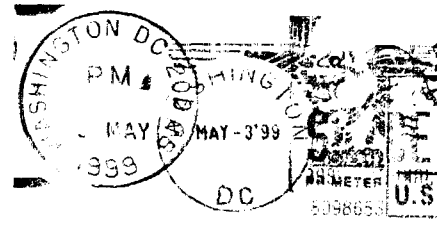

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